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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/365,677	08/02/1999	PING KUEN LAM	021234-1.00	2089

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FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/27/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/365,677	LAM ET AL.
	Examiner	Art Unit
	Anne-Marie Falk, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 June 2002 and 08 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6, 8-13, 15 and 17-30 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 8-13, 15, and 17-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed June 13, 2002 (Paper No. 10; hereinafter referred to as "the response") has been entered. Claims 1, 4, 8, 11, and 15 have been amended. Claims 7, 14, and 16 have been cancelled. Claims 18-30 have been newly added.

Accordingly, Claims 1-6, 8-13, 15, and 17-30 remain pending in the instant application. The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

The rejection of Claims 15-17 under 35 U.S.C. 112, first paragraph, are withdrawn in view of Applicants' arguments at pages 18-20 of the response.

Specification

The amendment filed June 13, 2002 (Paper No. 10) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendments designated amendments A-D, F, G, and J.

Numerous amendments rely on subject matter that is not included in the specification. Applicants have not pointed to appropriate support for these amendments **within the specification**.

Applicant is required to cancel the new matter in the reply to this Office Action.

With regard to the amendments that rely on the reference of Lam et al. (1998), which Applicants assert they have incorporated by reference, it is noted that a publication of this type may not be incorporated by reference. Thus, this is an improper incorporation by reference.

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The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added Claims 26-30 recite the new limitation “wherein the membrane has microholes of about 40 μm diameter.”

At page 16 of the response, Applicants state that support for this subject matter is found in the specification. However, for the reasons noted above, the specification is objected to where there is an attempt to newly introduce support for these claim limitations. At pages 16-17 of the response, Applicants again refer to the Lam et al. reference for describing the micropores of LASERSKINTM. This is improper support as the Lam et al. reference cannot be “incorporated by reference.”

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The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite because it depends from Claim 16, which has been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 stand rejected and Claims 1-6, 8-10, 15, and 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (1997) in view of Cooper et al. (1993), Hansbrough et al. (1989), and Myers et al. (1997), for reasons of record advanced on pages 7-9 of the Office Action of

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Paper No. 4 (mailed 6/20/01), on pages 8-9 of the Office Action of Paper No. 7 (mailed 2/26/02), and for the reasons set forth below.

The claims have been amended so that they now recite the use of **human** dermal fibroblasts and/or **human** keratinocytes and sometimes a **human** patient.

With regard to the Della Valle (1997) reference, Applicants argue (at page 22 of the response) that Della Valle's 3T3 cells are removed when "all traces" of the culture medium are removed by a wash with a physiological solution. Applicants point to Della Valle at Column 5, lines 50-55, and conclude that Della Valle's "artificial skin therefore does **not** have any fibroblasts" (original emphasis). However, this section does not in any way refer to removing cells, but rather only refers to removing **culture medium**. The 3T3 cells are already adhered to the membrane (see Column 5, lines 3-14) and are underneath a layer of human keratinocytes. Although Della Valle does not disclose the use of human fibroblasts, Hansbrough et al. (1989) clearly discloses the successful use of **autologous, proliferative human** fibroblasts and **human** keratinocytes (page 2126, column 1, lines 9-11) in preparing graftable skin material in 1989. Thus, one of skill in the art would have been motivated to substitute human fibroblasts for the mouse 3T3 fibroblasts for use of the graftable skin material in humans.

In response to Applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller* 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.* 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

At page 25 of the response, Applicants argue that Myers et al. is basically redundant of the Della Valle reference. However, Myers et al. emphasizes the importance of providing a dermal bed for better take rates of cultured keratinocyte autografts (line 1 of Abstract). The reference specifically teaches that the dermal wound bed should be prepared so that it provides a surface of live and autologous cells (page 221, column 2, paragraph 1). Applicants argue that there is no suggestion for "a second layer of viable

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human dermal fibroblasts upon an upper side of said biosynthetic substratum.” However, since Myers et al. emphasizes the importance of preparation of the dermal wound bed (a recognized need), one of skill in the art would have recognized that this could be done by providing a material that has keratinocytes seeded on both sides of the biosynthetic substrate. Thus, the need recognized by Myers et al. accompanied by the availability and commonplace use of biosynthetic substrates seeded with keratinocytes on the surface, would have led the skilled artisan to produce a material with keratinocytes on both sides of the biosynthetic substrate.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tiffiany Tabb, whose telephone number is (703) 305-1238.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER